

EXHIBIT 73

PLAINTIFFS' EXHIBITS 000101

From: Paul Galea <pgalea@actavis.com>
Sent: Monday, February 2, 2009 3:54 PM
To: Tony Delicato <TDelicato@actavis.com>
Subject: QRB minutes
Attach: QSD-141_QRB minutes_01_09.pdf

Hi Tony,

Please find attached.

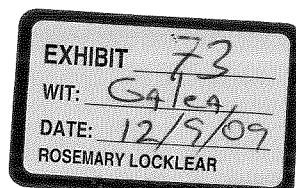


Paul Galea
QA Director, Documentation
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NJ 07424 Little Falls USA f mp_ofax w mp_oWeb

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PLAINTIFFS' EXHIBITS 000102





Quality Review Board

Meeting date: January 26, 2009.

Attended: Tony Delicato, Misbah Sherwani, Elisabeth Guarch, Brian Nizio, Dorota Sobczyk, Jason Ellis, Ashesh Dave, Mike Puorro, Michael Redmond and Marjorie Demko

Absent: Jacob Haroon, Annie Cheung and Vince Warren

Meeting chaired by: Paul Galea

Meeting Minutes:

All provided metrics were reviewed during the meeting. There were no metrics which were indicative of negative trends. Refer to Annex I for QRB presentation.

No QC metrics were provided for this meeting.

Training:

Out of 26 departments 14 are less than the target of 90%. Of these 38% are less than 85% trained. The site training percentage has risen to 75% from 74% in December 2008. This is still low compared to the target of 90%

Recall: no metrics available.

Expired SOPs:

In all five SOPs are still expired. These will be addressed by the owners by the next QRB meeting.

Change Control:

Target date for implementation of Trackwise was confirmed for January 30. No new change controls will be issued in the paper system after this date. Existing change controls will be closed as per system they were initiated in.

Annual Product Reviews:

All APRs issued on target. Positive trend maintained for four months.

CAPA:

All 2008 CAPAs have extension reports in place. QC CAPAs to be verified for the exact number still open.



Quality Review Board

Investigations:

The average cycle time for closure of lab related investigations went down to 17 days during the month of January. No investigations were open for more than 30 days. This trend has been steadily maintained for lab and non lab investigations since Jul 2008 (exception being for August where the non lab were at 31 days).

Complaints:

63 AE complaints were closed in January with an average cycle time of 70 days to close.

Facilities and Preventative Maintenance:

Percentage closed is 100% and on target.

Calibrations:

The decrease in total active records is because the decommissioned equipment is no longer being reported. Only 42% is given as completed on time, reason being that the month was not yet over.

Discussion:

During the meeting it was decided to obsolete SOP 0063 Qualification of Production Areas. This will be assigned as an action item to Technical Services.

The action item to indicate the training status for Managers is still open. Action assigned to training Department.

The action item for the setup of a separate CAPA meeting is still open. Action assigned to QAIG.

QSIP metrics shall be included in QRB as from next meeting.

QRB meeting for February shall be held in the first week of March in order to have metrics for the full month. This will be done for all upcoming meetings going forward.


Paul Galea
Director, Documentation
February 2, 2009.

APPENDIX I

PLAINTIFFS' EXHIBITS 000105



Quality Review Board
Actavis Teijow LLC

Meeting # 5 - January 26, 2008



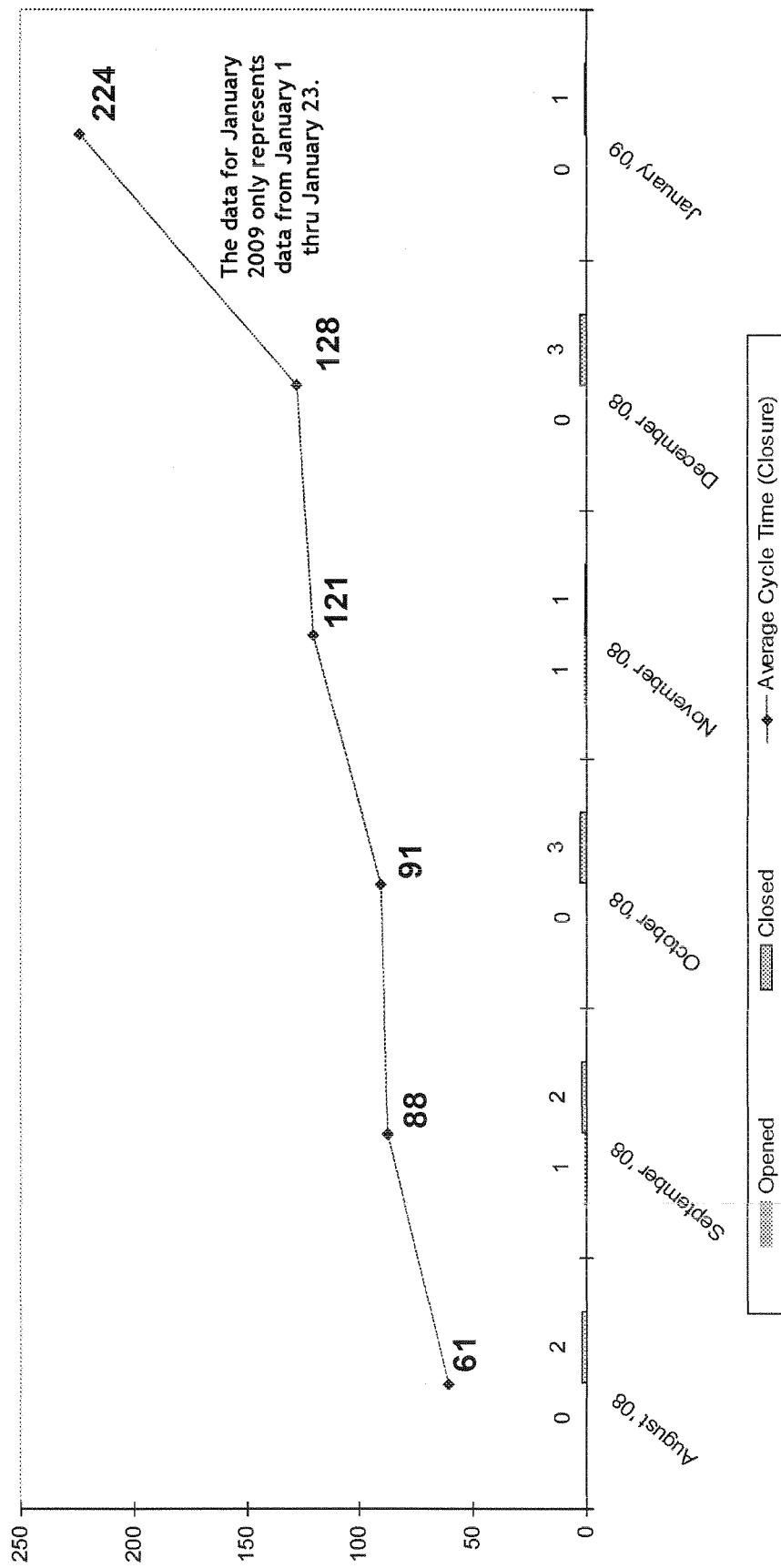
PLAINTIFFS' EXHIBITS 000106



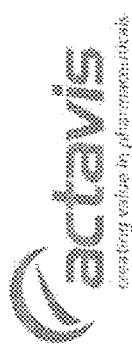
Quality Review Board

January 2009

Little Falls Product Complaints



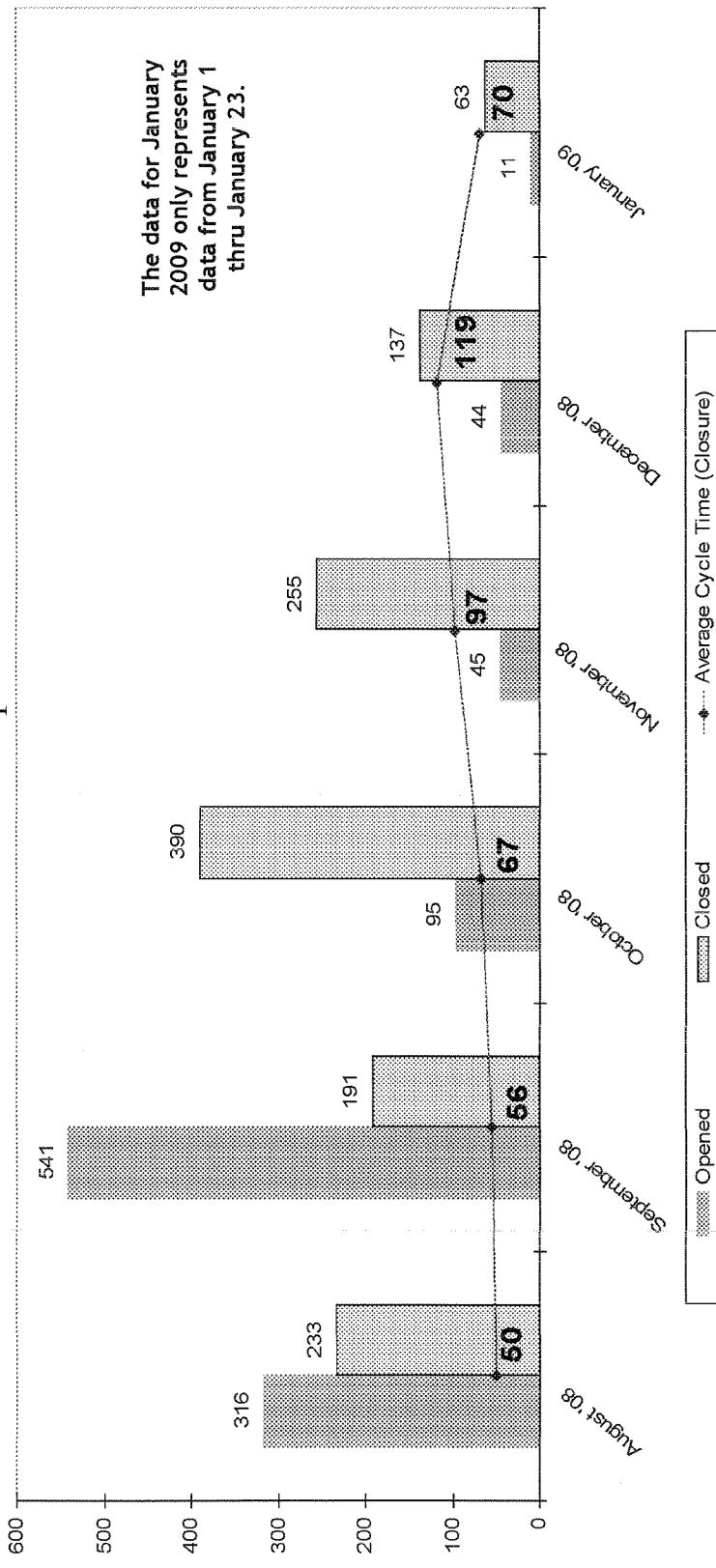
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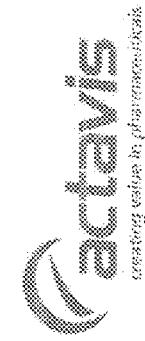
Quality Review Board

January 2009

* Little Falls AE Complaints



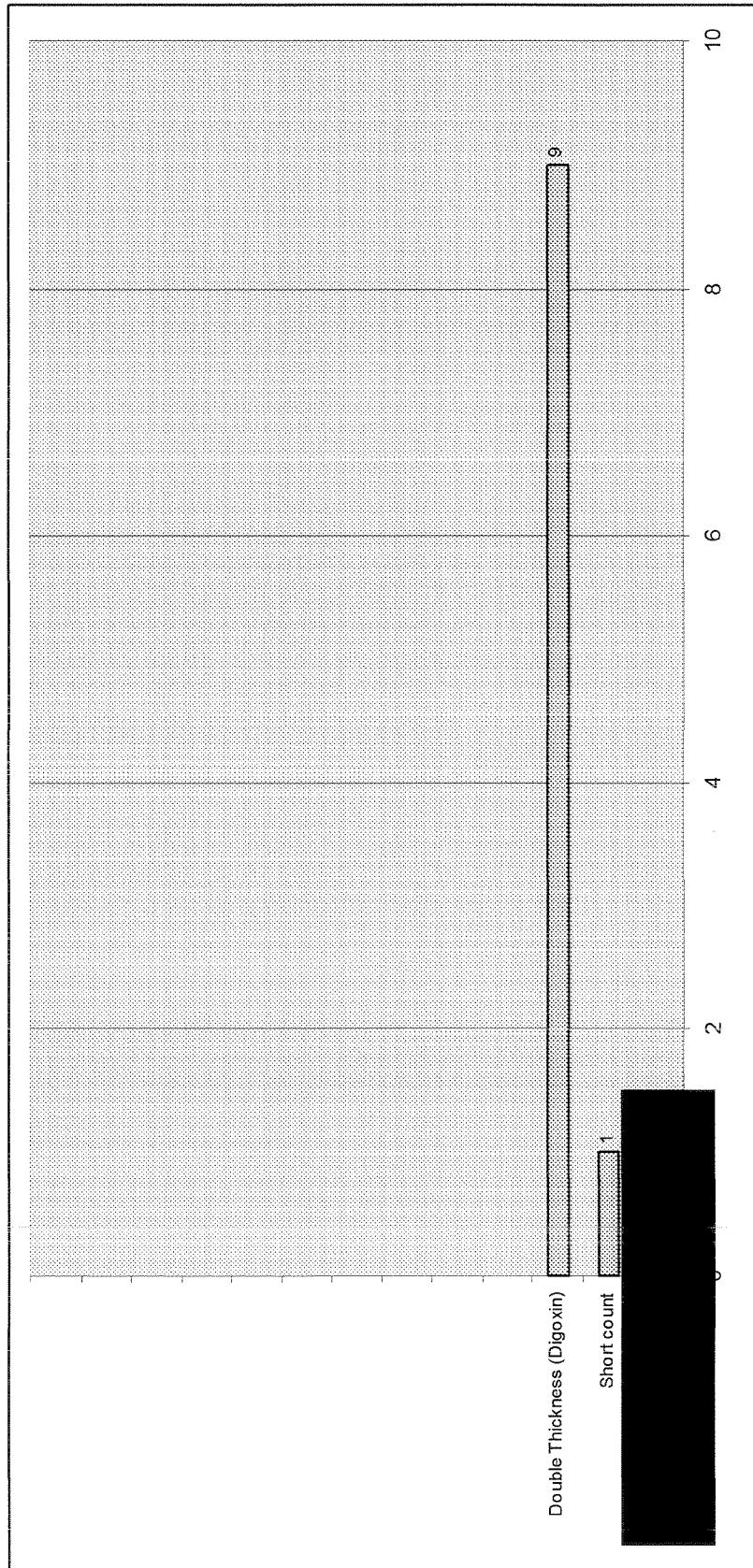
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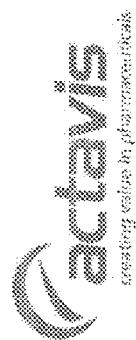
Quality Review Board

January 2009

Little Falls Product Complaints by Category (August 2008 to January 2009)



PLAINTIFFS' EXHIBITS 000109



Deviations and CAPA Partial Data (ending 1/23/09)

PREVENTIVE ACTIONS - Little Falls as of 1/23/09

	Remaining From 2008 Mutual System	DEC 2008 New System	JAN 2009 New System
Total Due	N/A	12	8
Total Open	47	9	4
% Overdue	24	0	0
% Overdue	51%	0%	0%
CAPA Completed	N/A	3	4
# CAPA Completed On Time	N/A	1	4
% CAPA Completed On Time	N/A	33%	100%

Data does not include Corrective Actions (immediate actions); only PAs Preventive Actions



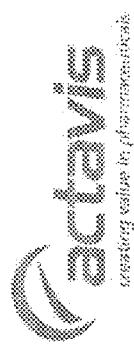
Monthly Report

January 2009

Overview of Open CAPAs by Department (Preventive Actions only) as of 1/23/09

Department	# of PAs manual system	# of PAs TW system	# of PAs Manual system	# overdue TW	# overdue TW
AR	7	1	4	0	0
ENG	8	3	3	0	0
MFG	6	1	6	0	0
PKG	1	0	1	0	0
QA	4	1	3	0	0
QC	14	4	6	0	0
RA	1	0	1	0	0
RD	2	0	0	0	0
Validation	4	3	0	0	0
Total	47	13	24	0	0%
		% Overdue	51%		

Includes 2008 data in totals



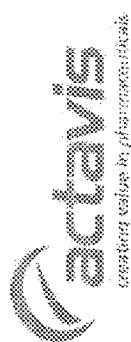
Monthly Report

January 2009

Deviations Investigations: Non-Laboratory vs Laboratory - Little Falls

	Totals	Non Laboratory	Laboratory
January 2009 As of 1/23/09			
Total Initiated (20 total)	20	4	16
Total Closed (w/in Month)	2	0	2
Total Open (at month end) YTD	18	4	14
Total Open > 30 days	0	0	0
Oldest Open (days)	N/A	N/A	N/A

PLAINTIFFS' EXHIBITS 000112



Monthly Report

January 2009

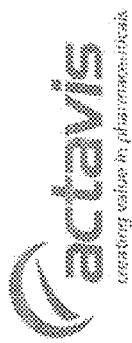
Detailed Information for

Non-Lab Deviations vs Laboratory Deviations

Exceeding 30 days

Inv #	Date Issued	Batch #	Product #	Product Name	Extension date	Days Open
Not applicable - no deviations over 30 days						

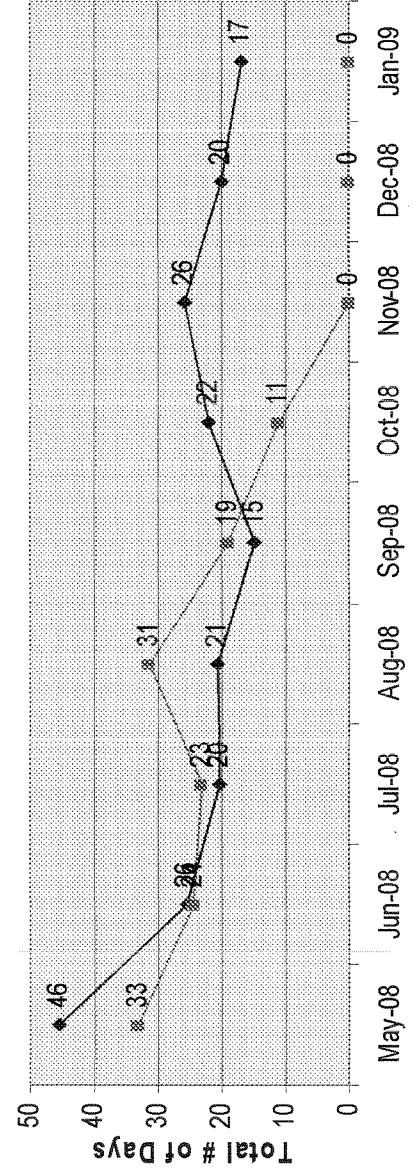
PLAINTIFFS' EXHIBITS 000113



Monthly Report

January 2009

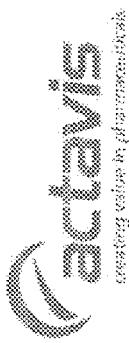
Average Cycle Time to Closure
Trend Since May 2008



Cycle time based on closed Deviations only

Zero (0) deviations for Non Lab Deviations indicates that none were closed during that reporting month

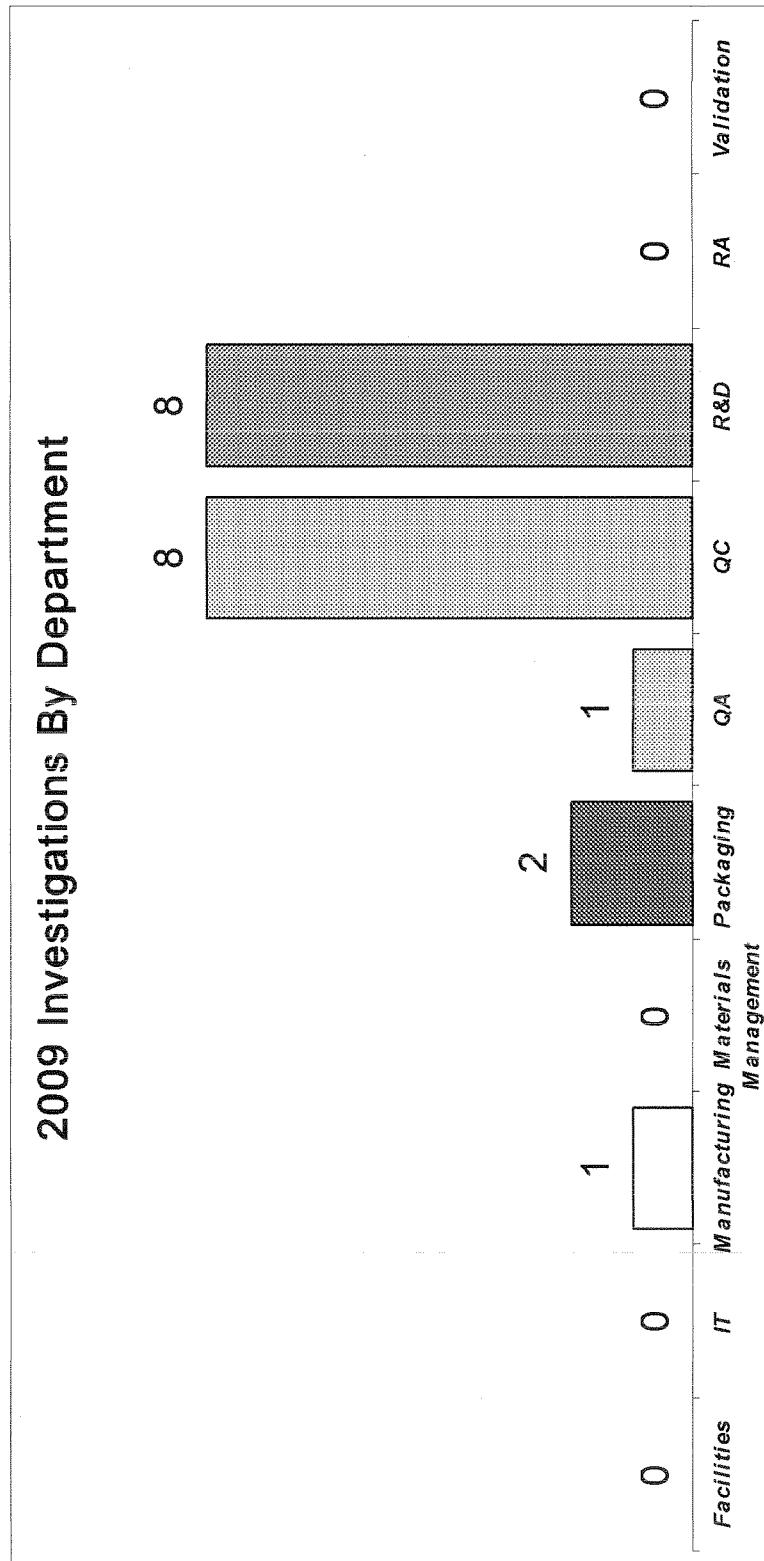
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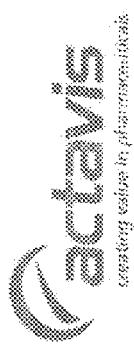
Monthly Report

January 2009

2009 Investigations By Department

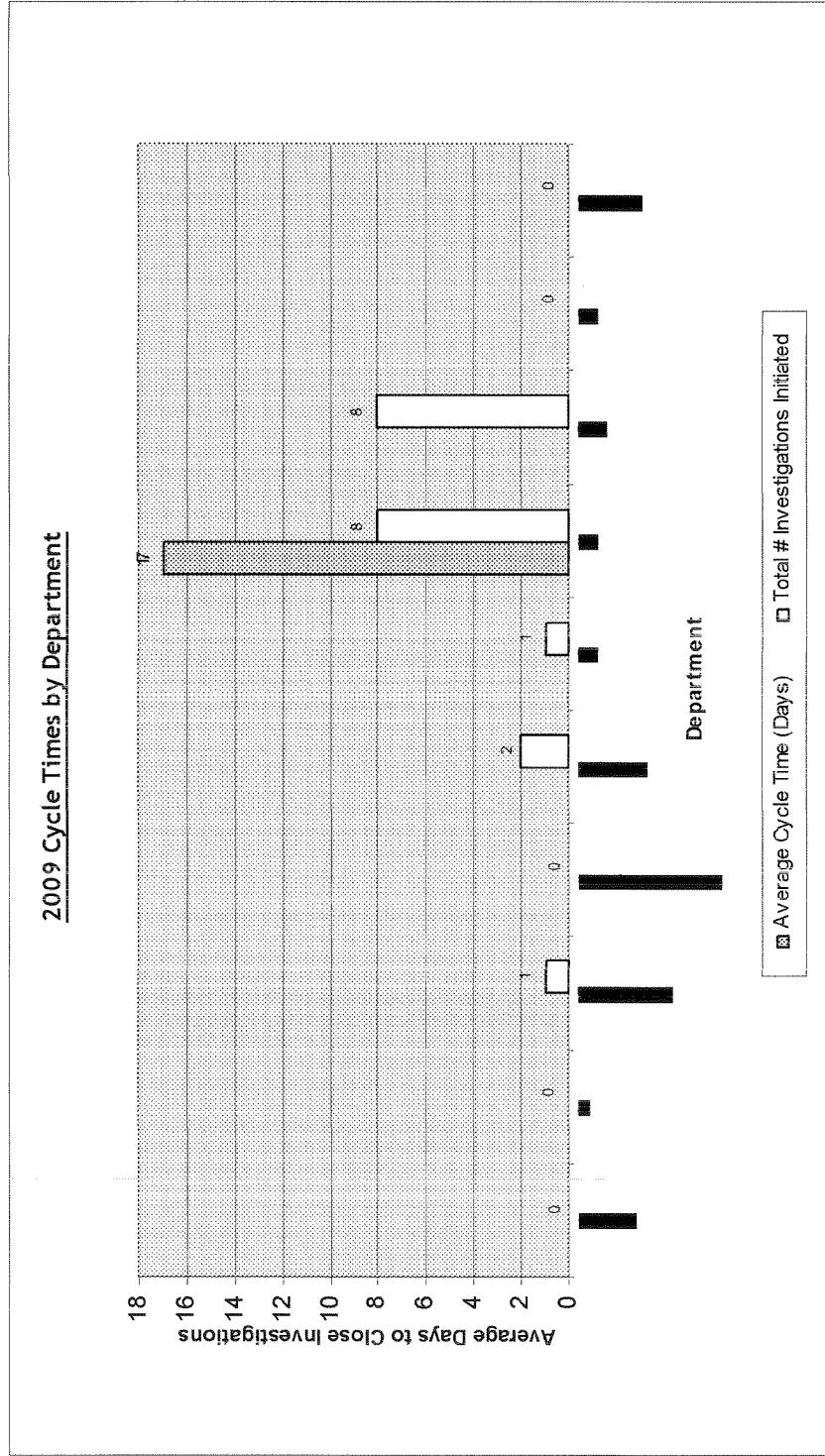


PLAINTIFFS' EXHIBITS 000115



Monthly Report

January 2009

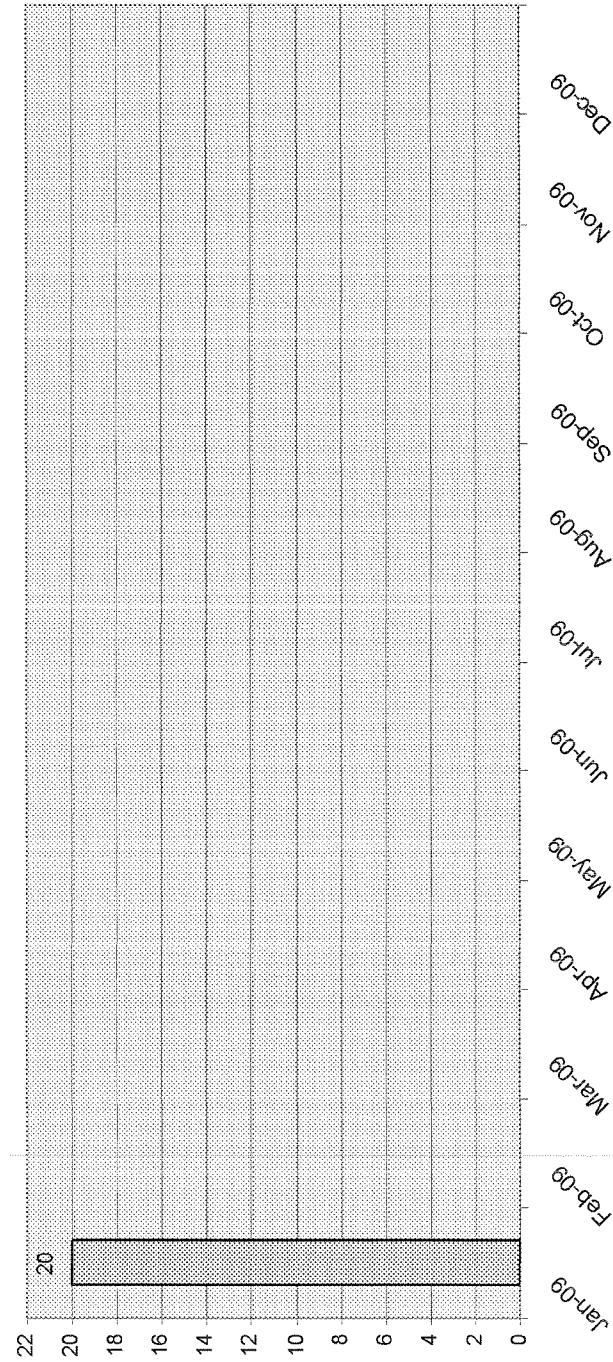




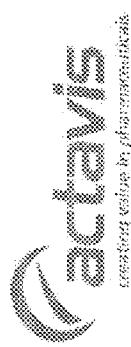
Monthly Report

January 2009

2009 Investigations Monthly
Total # Opened per Month



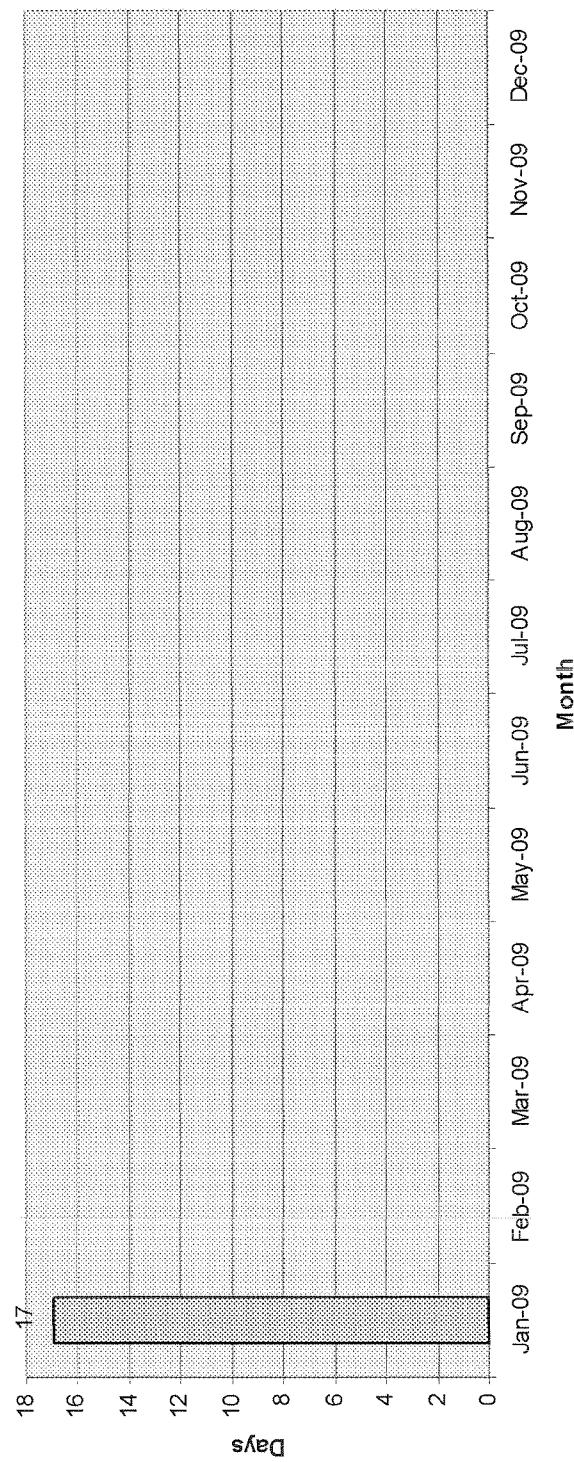
PLAINTIFFS' EXHIBITS 000117



Monthly Report

January 2009

Average Monthly Cycle Time For Investigation Closure



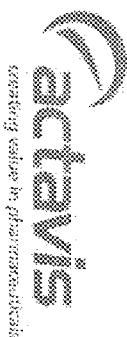
PLAINTIFFS' EXHIBITS 000118

Totowa Site Training Assessment

Month	% Completed Training for All Positions
October	56%
November	57%
December	74%
January '09	75%

Note: Data is impacted by changes to training requirements (syllabi), new employees and terminated employees.

The data reported reflects training records received/entered through January 22, 2009.
Training records received after this date will be reported in the next report.



Training

Departments less than 90%

Department	%
Operations Admin	70%
Engineering Admin	65%
QA Investigations	84%
QA Documentation	87%
Site Training	86%
Regulatory Affairs *	38%
Research & Development	36%

Department	%
Product Development	45%
Shipping & Receiving	48%
Purchasing	38%
Supply Chain	89%
Human Resources	70%
EHS	18%
Site Security *	37%

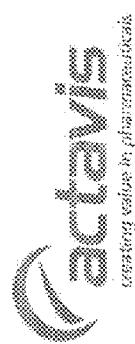
Total Departments = 26

Total less than 90% = 14

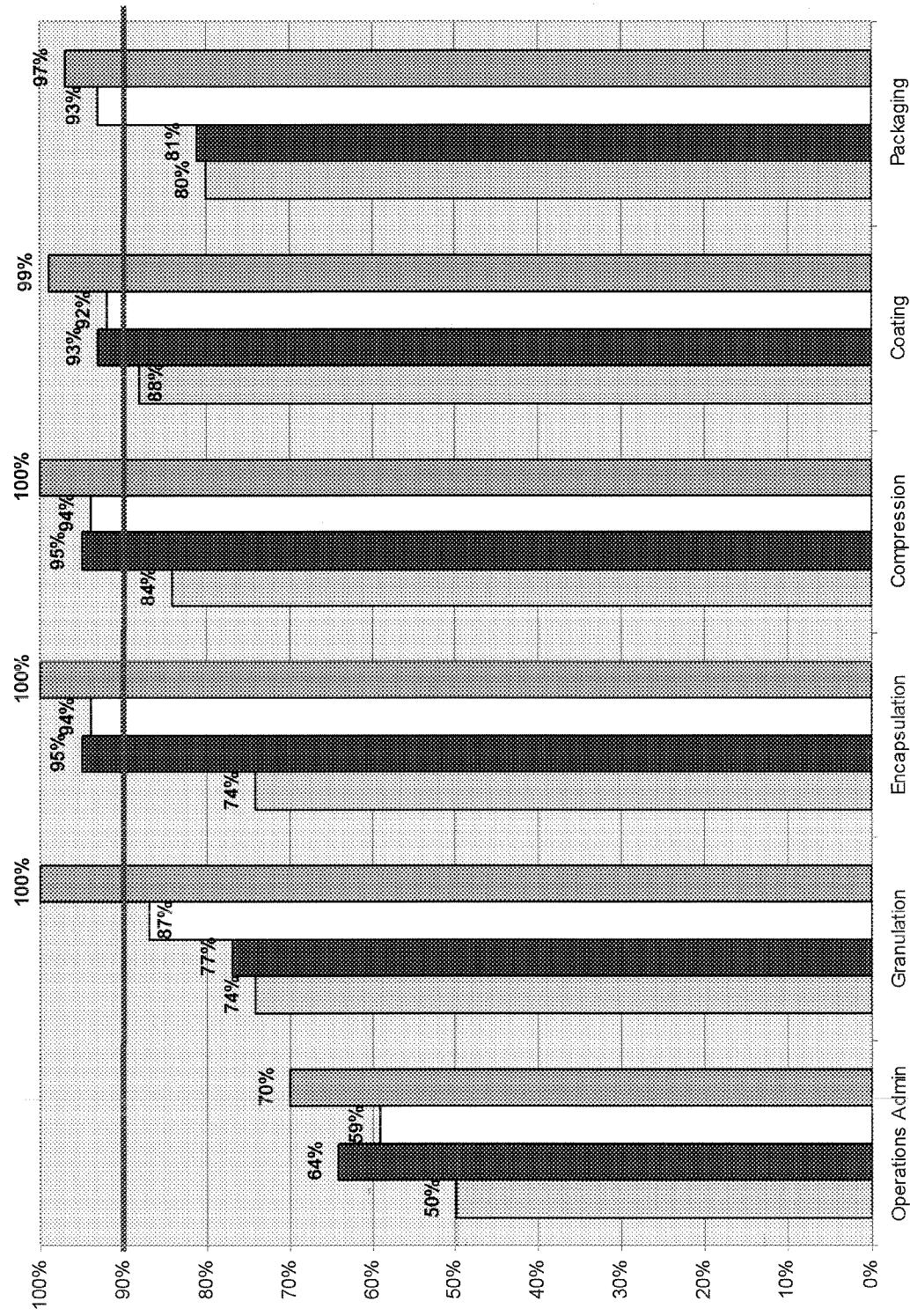
53% are less than 90%

38% are less than 85%

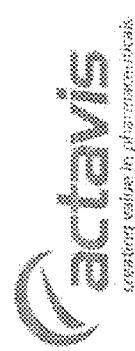
* Syllabi adjustment in progress



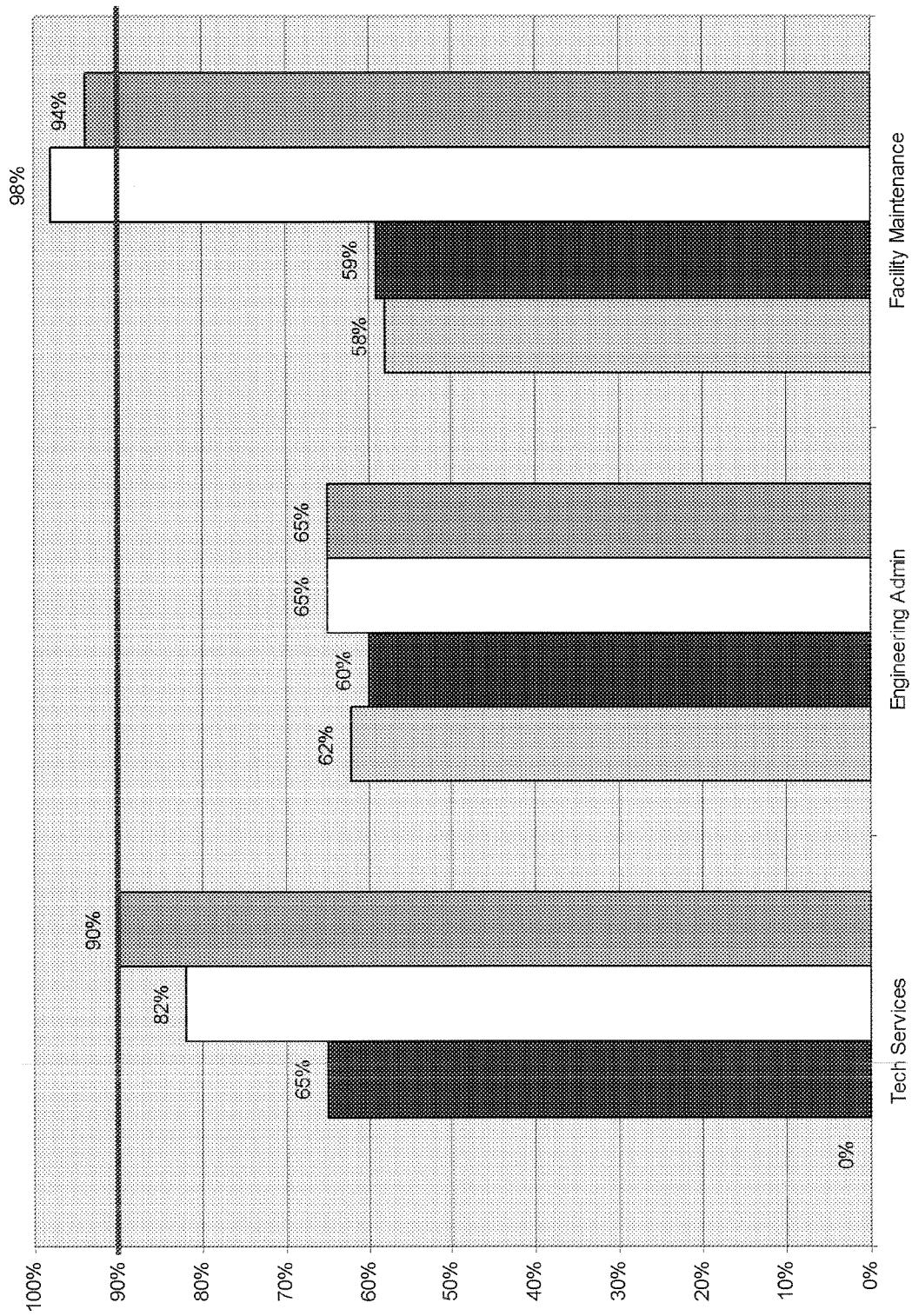
Training



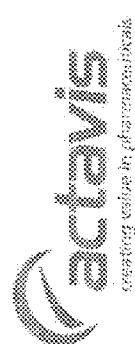
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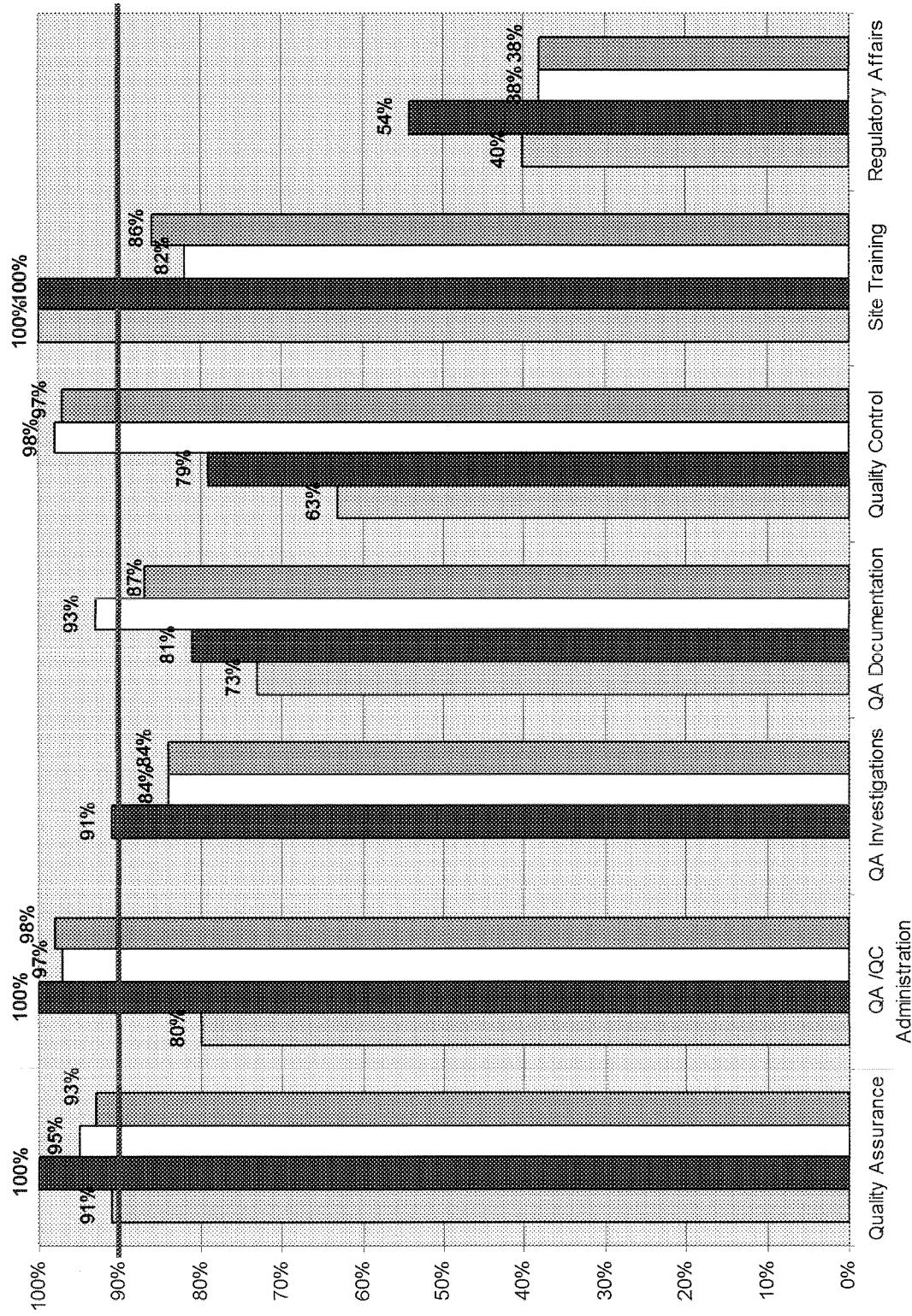
Training



PLAINTIFFS' EXHIBITS 000122



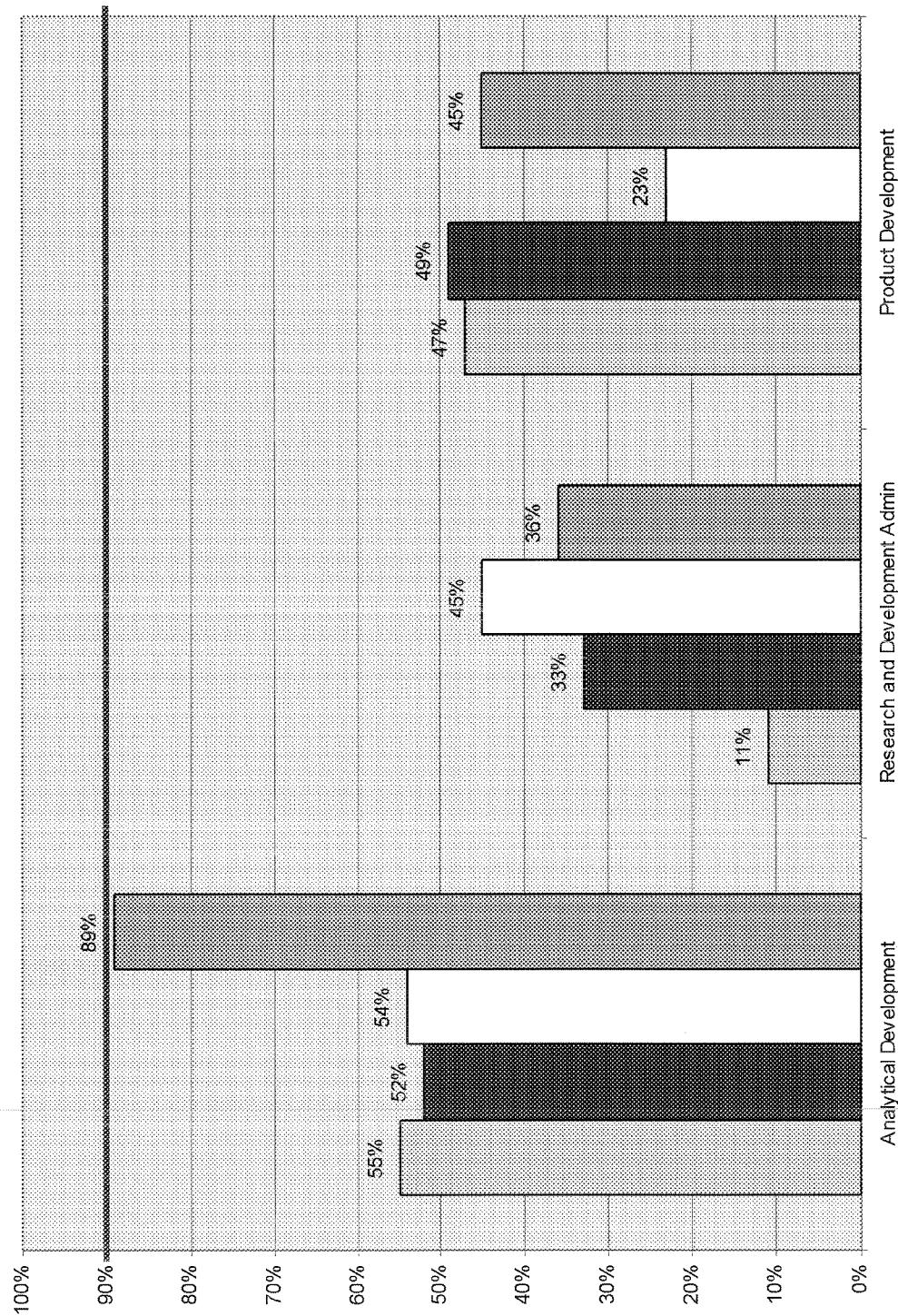
Training



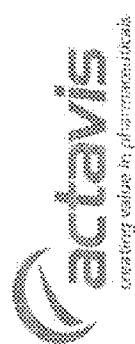
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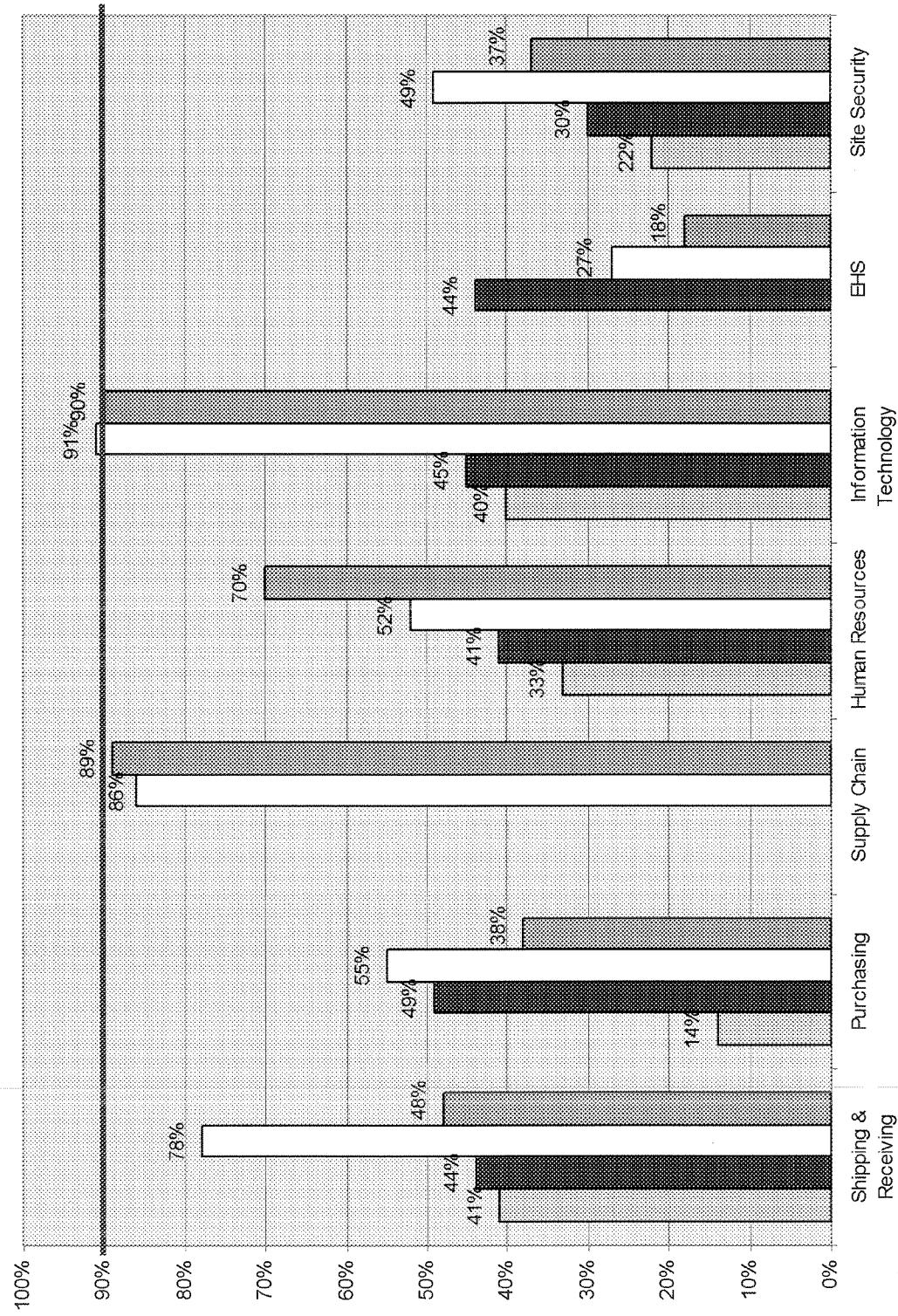
Training



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Training



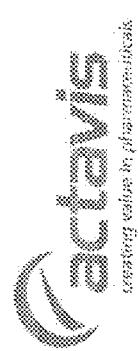
PLAINTIFFS' EXHIBITS 000125



Training

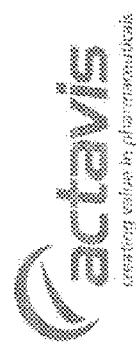
New QRS Requirement

- * All departments must target 90% for completed training
 - * Site Training will provide the necessary information, work with each group and will follow-up to meet the goal.
- * NEW CAP (Competency Assessment & Performance) - Training System
 - * Online Training & Assessments (View your training gaps anytime)
 - * Web-based application (access from anywhere)
- * Learning Management System (LMS)
 - * Web-Based application (access from anywhere)
- * Divisional Training Courses (All US sites)
 - * GMP Training
 - * Train-The Trainer
 - * Corporate Training
- * Validation to begin - Q1 2009; Target to implement CAP - Apr. 09



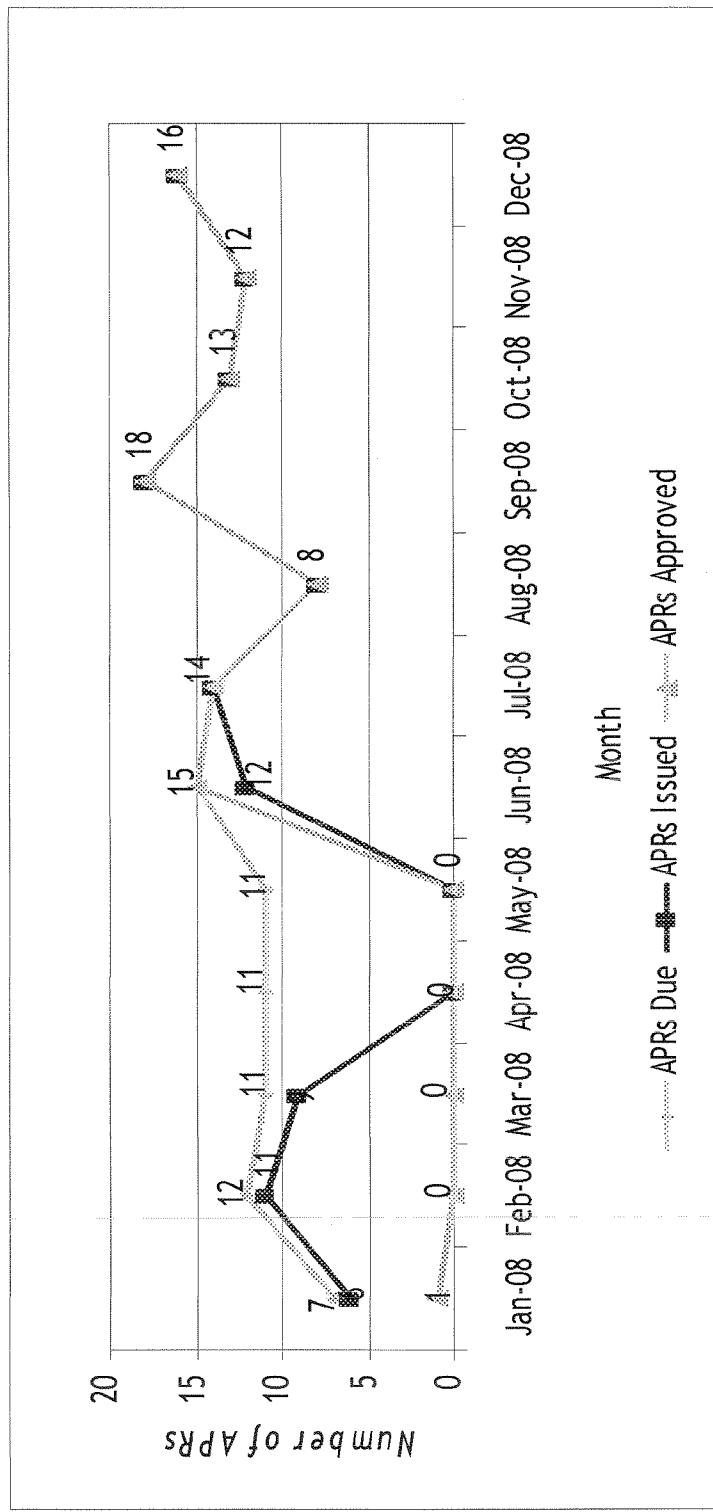
Training

- ❖ Monthly Training Reports are targeted to be distributed to Training Contacts & Department Management within the 1st week of each month



APRS

Figure 1 Number of APRs Due, Issued, and Approved (Monthly Basis)

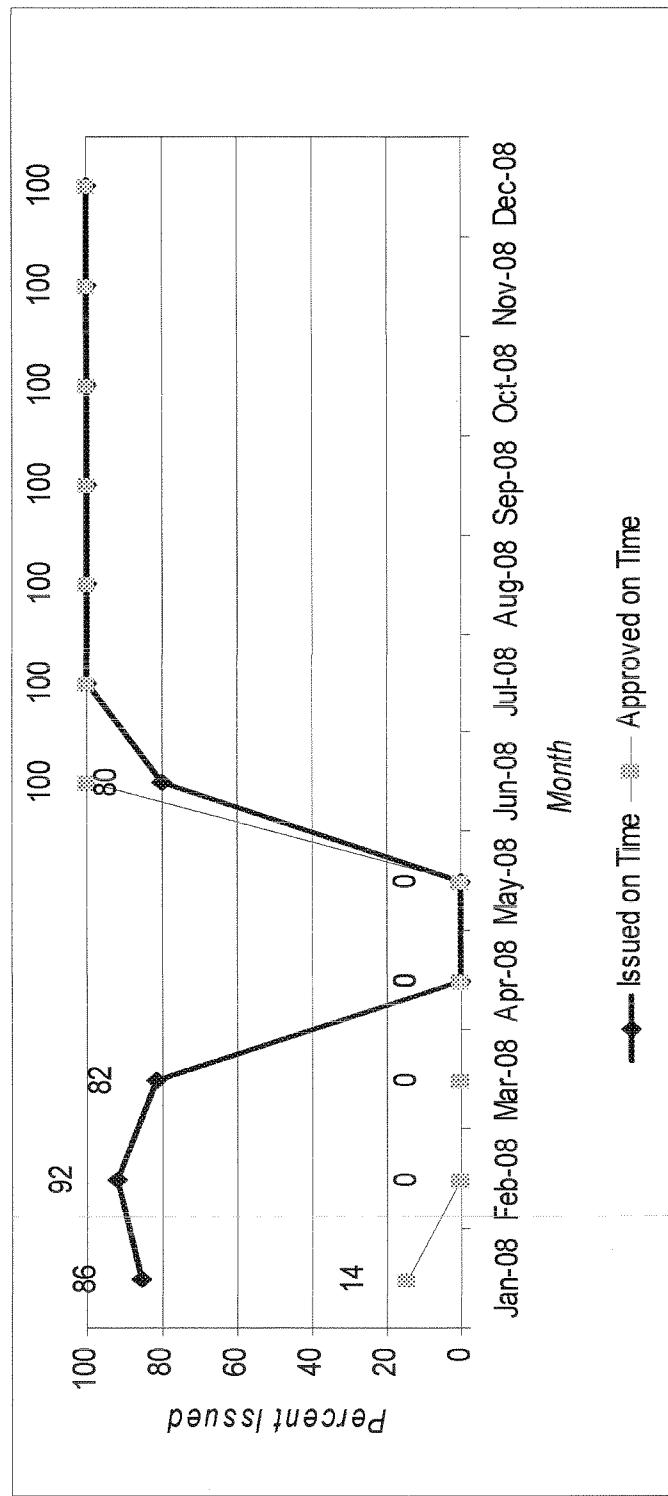


PLAINTIFFS' EXHIBITS 000128

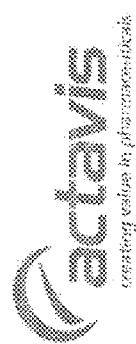


APRS

* Figure 2 Percentage of APRS Issued and Approved on Time
(Monthly Basis)

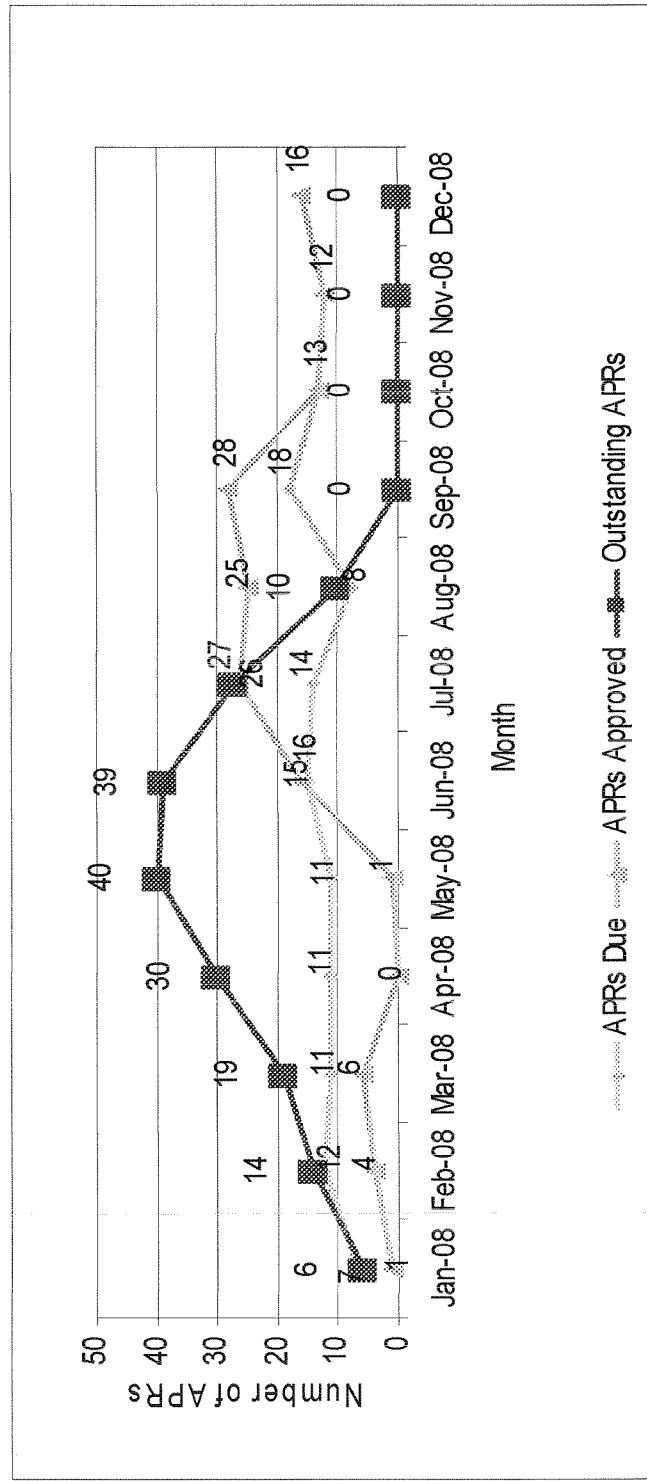


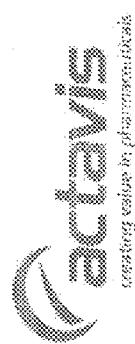
PLAINTIFFS' EXHIBITS 000129



APRS

* Figure 3 Number of APRs Due, Outstanding, and Approved (Monthly Basis)

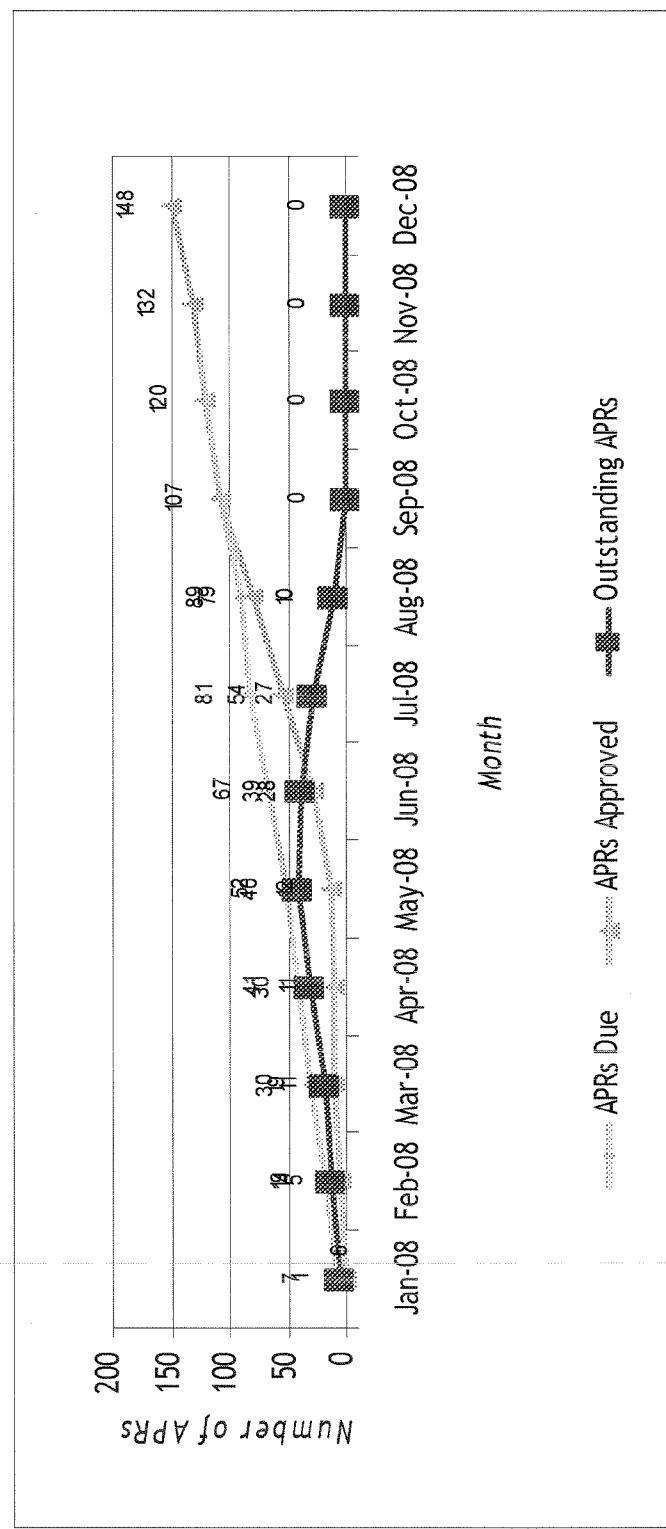




APRS

Figure 4
Date

Number of APRs Due and Approved Year-to-

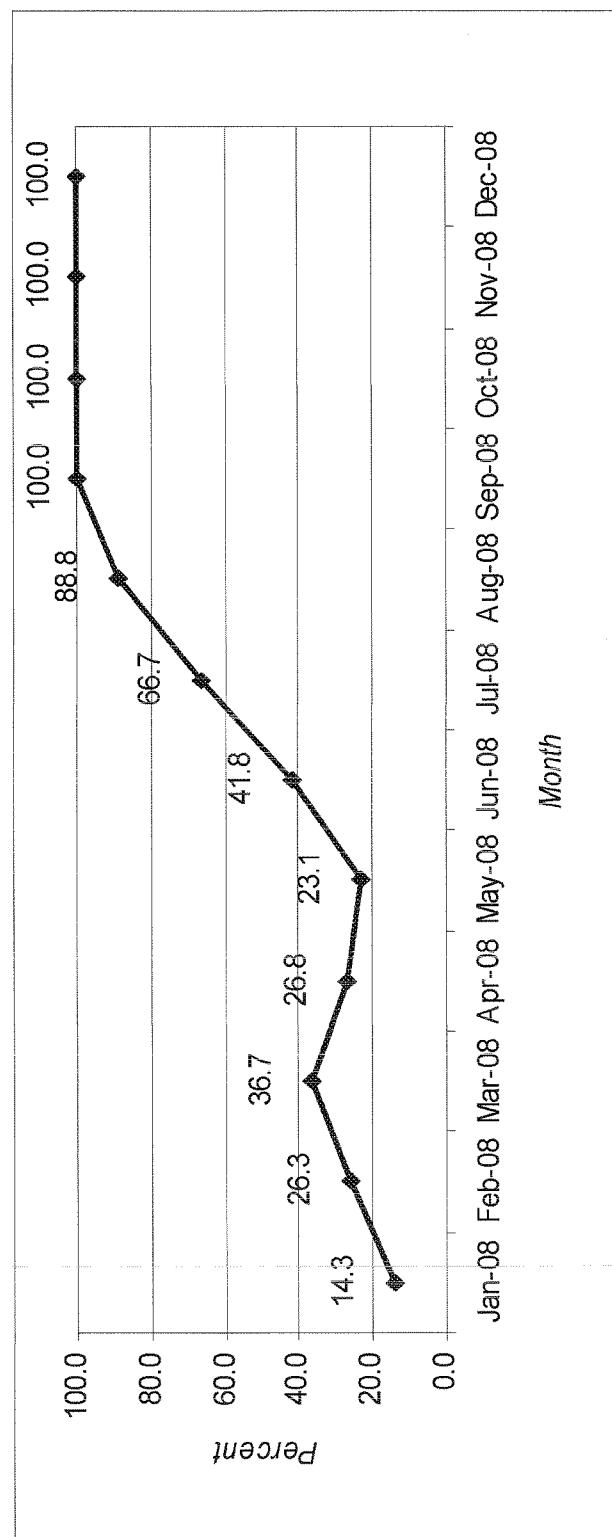


PLAINTIFFS' EXHIBITS 000131



APRS

* Figure 5 Percentage of APRs Approved Year-to-Date



PLAINTIFFS' EXHIBITS 000132

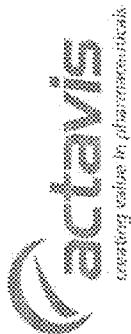


Expired SOPs

SOP_No	Iss	SOP_Title	Implemen
0063	02	Qualification of Production Areas	03-Jan-06
0067	00	Technology/Product Transfer	01-May-00
0068	01	Setting Specifications	07-Nov-05
0029	00	R & D Batch Conversion	19-Aug-92
0032	04	Control of Contract Processing Operations	07-Nov-05

PLAINTIFFS' EXHIBITS 000133

Change Control



Issued:	Approved:	Rejected:	Open >90 days:
32	11	1	12
*	*	*	*

PLAINTIFFS' EXHIBITS 000134

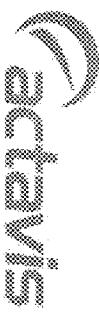


Change Control

CHANGE CONTROL FLOW WORKSHEET 2008

CC #	Doc #	Type	Current Rev#	Doc Name	Date Initiated	Owner	Department	To Be Chased	Date Sent	Status
CC007	Rev-AD-352-02	ASCP	N/A	Propoxyphene Hydrochloride, USP	04/01/08	E. Murphy	QC	New specification sheet/retest report for new material	05/03/08	In Progress/For test
CC018	PRO-351	ASCP	01	As. Pseudoephedrine HCl, NF	05/21/08	A. Pash	QC	Specification for 10% ephedrine hydrochloride tablet 30 tablets, the particle size test specification for weight 20-15 corrected from NSC 10.0% to NSC 10.0% due to 30% loss of drug substance, error etc.	05/26/08	In Progress/Correction
CC050	N/A	N/A	N/A	Packaging components closure ID # 7934, 7955, 7971, 7972, 7975 and 7978	06/13/08	C. Ashe	8KG	as a part of standardization of closures in packaging area by releasing PC 22 liner and induction seal without issue to all closures as descriptive seal with liner. This is an improved test for product protection	06/19/08	O. Joshi - Review
CC067	Rev-3000-05	Rev-3000-PFT-03	N/E	Acetaminophen, Sodium, NF	03/05/08	J. Sartori	QC	Comments issued with ID # 3000, Rev # 02 & released to the eliminated reduce testing, coordinated QC test, dated 1/28/08 updated to include the release of method # Rev-3000-PFT-03 per investigation # 02-035	03/05/08	In Progress/Correction
CC077	WCH-20-0259	ASCP	02	Propoxyphene Bitartrate, USP	02/11/08	S. Sarker	AR	Specifications for 200 mg tablet updated as per UEP process batch effective 02/07/08	02/21/08	In Progress
CC092	N/A	Equipment	N/A	PTK 29-2008 Tablet Press ID # 00384	02/17/08	J. Bladon	KFD	The software for the tablet press was upgraded from version Blister T2.5 to Blister T2.4	10/25/08	End-Search Review
CC110	N/A	N/A	N/A	Merck Tablets - Acetylpromazine, ID # 2286	03/27/08	S. Sarker	AR	Enclosure major update of the baseline and performance	01/26/09	Re-approval

PLAINTIFFS' EXHIBITS 000135



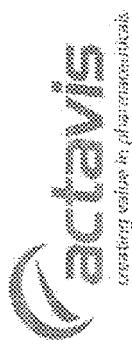
PMs
January 2008

Facilities PM's/Work Orders

Preventive Maintenance Metrics

	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	YTD 2008
Work Orders Safety/Emergency/Near Miss	N/AV	N/AV	0					0
Work Orders Safety/Emergency/Near Miss Closed	N/AV	N/AV	0					0
Total PM's Active (Closed)	N/AV	N/AV	218	183	161	206	148	916
Weekly PMs Backlogged > 1 day	N/AV	N/AV	0	0	0	0	0	0
BWeekly PMs Backlogged > 2 days	N/AV	N/AV	0	0	0	0	0	0
Monthly PMs Backlogged > 7 days	N/AV	N/AV	0	0	0	0	0	0
Bimonthly PMs Backlogged > 10 days	N/AV	N/AV	0	0	0	0	0	0
Offly PMs Backlogged > 14 days	N/AV	N/AV	0	0	0	0	0	0
Semi Annual PMs Backlogged > 21 days	N/AV	N/AV	0	0	0	0	0	0
Annual PMs Backlogged > 30 days	N/AV	N/AV	0	0	0	0	0	0
Biennial PMs Backlogged > 30 days	N/AV	N/AV	0	0	0	0	0	0
PMs for the Month Closed %	N/AV	N/AV	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Work Orders Requested	N/AV	N/AV	31	34	28	32	21	146
Work Orders Closed	N/AV	N/AV	31	34	28	32	21	146
Total PM/PMs Committed for Month	0	0	249	217	189	238	165	1058

Note:



Calibrations

January 2008

Facilities PM's/Calibrations

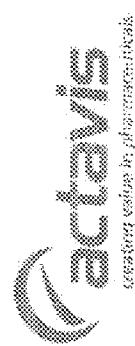
- * Calibration Metrics

	Oct 08	Nov 08	Dec 08	Jan 09
Total Due	64	99	191	65
% Completed on Time	98%	100%	100%	42%*
New Connections (Month)	2	0	0	0
New Connections Average	19	39	25	30
Total Active Calibrations	891	916	941	895
Completed Out of Service	2	3	1	1

*Partial Month - work in progress

Added TP-0085 and TP-0086 PTK Presses (30 calibrations)

WT-AMW03 OOT, investigation initiated in Trackwise.



Action Items

- * Manager and Director Training Syllabi need to be highlighted and for this reason they will be presented as a separate metric. This will be put down as an action.
- * The number of expired SOP has fallen down to 7. These shall be closed by the 20th of January 2009.
- * 51 overdue for closeout and a good percentage arise from investigations. All the open CAPAs for [REDACTED] and General GMP need to be addressed in a separate meeting.

PLAINTIFFS' EXHIBITS 000138